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| APPLICATION NO.  | FILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|--------------|----------------------|---------------------|-----------------|
| 10/522,662   | 09/09/2005   | Xiaozhuo Chen        | 27211/04134         | 8686            |
| 24024 7590 01/17/2008<br>CALFEE HALTER & GRISWOLD, LLP |              |                      | EXAMINER            |                 |
| 800 SUPERIOR AVENUE                                    |              |                      | MAIER, LEIGH C      |                 |
| SUITE 1400<br>CLEVELAND,                               | OH 44114     |                      | ART UNIT            | PAPER NUMBER    |
| CEEVEEIMO  | , 022 1122 1 |                      | 1623                |                 |
|  |              |                      | MAIL DATE           | DELIVERY MODE   |
|  |              |                      | 01/17/2008          | PAPER           |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| -   |   | Application No.  | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|--|
| Office Action Summary   |   | 10/522,662   | CHEN ET AL.  |  |  |  |  |
|   |   | Examiner   | Art Unit   |  |  |  |  |
|   |   | Leigh C. Maier   | 1623   |  |  |  |  |
| Period fe   | The MAILING DATE of this communication app  | ears on the cover sheet  | with the correspondence address  |  |  |  |  |
|   | ORTENED STATUTORY PERIOD FOR REPLY  | VIC SET TO EVOIDE 4  | MONTH(S) OR THIRTY (30) DAYS   |  |  |  |  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failt<br>Any  | CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 (SIX (6) MONTHS from the mailing date of this communication. Disperiod for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUN<br>36(a). In no event, however, may<br>will apply and will expire SIX (6) MO<br>, cause the application to become | APANDONE  NICATION.  a reply be timely filed  DNTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |  |
| 1)[   | Responsive to communication(s) filed on   | _•   |  |  |  |  |  |
| 2a) <u></u> ☐   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |  |
| 3)□   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |  |
|   | closed in accordance with the practice under E  | x parte Quayle, 1935 C.  | D. 11, 453 O.G. 213.   |  |  |  |  |
| Disposit  | ion of Claims   |  |  |  |  |  |  |
| 4)⊠   | 4)⊠ Claim(s) <u>1-24</u> is/are pending in the application.   |  |  |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5)□   | 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
|   | Claim(s) is/are rejected.   |  |  |  |  |  |  |
| · _   | Claim(s) is/are objected to.  |  |  |  |  |  |  |
| 8)⊠   | Claim(s) <u>1-24</u> are subject to restriction and/or e  | election requirement.  |  |  |  |  |  |
| Applicat  | ion Papers  |  |  |  |  |  |  |
| 9)[   | The specification is objected to by the Examine   | r.   |  |  |  |  |  |
| 10)[  | The drawing(s) filed on is/are: a) acce   | epted or b) objected to  | by the Examiner.   |  |  |  |  |
|   | Applicant may not request that any objection to the   | drawing(s) be held in abeya  | ance. See 37 CFR 1.85(a).  |  |  |  |  |
| _   | Replacement drawing sheet(s) including the correcti   | *  |  |  |  |  |  |
| 11)   | The oath or declaration is objected to by the Ex  | aminer. Note the attache   | ed Office Action or form PTO-152.  |  |  |  |  |
| Priority ι  | ınder 35 U.S.C. § 119   |  |  |  |  |  |  |
| 12)   | Acknowledgment is made of a claim for foreign   | priority under 35 U.S.C.   | § 119(a)-(d) or (f).   |  |  |  |  |
| a)  | a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.   |  |  |  |  |  |  |
|   |   |  |  |  |  |  |  |
|   | 2. Certified copies of the priority documents   | s have been received in  | Application No   |  |  |  |  |
|   | 3. Copies of the certified copies of the prior  | ity documents have bee   | n received in this National Stage  |  |  |  |  |
|   | application from the International Bureau   | , , , ,  |  |  |  |  |  |
| * 5   | See the attached detailed Office action for a list of   | of the certified copies no   | t received.  |  |  |  |  |
|   |   |  |  |  |  |  |  |
| A44a-b  | M-1   |  | ·  |  |  |  |  |
| Attachmen   | t(s) e of References Cited (PTO-892)  | 4) [] Inton-i  | Summan, (DTO 412)  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date   |   |  |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other: |   |  |  |  |  |  |  |
| i-ape   | 1 110(S) Wall Date  | Of Lift Outer:   | <del></del> ·  |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20, drawn to therapeutic methods comprising administration of gallotannins and derivatives thereof.

Group II, claims 21-24, drawn to gallotannins and derivatives thereof and compositions thereof.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature that is novel and contributed by Applicant. The feature common to both the inventions is the requirement for a gallotannin or derivative thereof. However, these compounds are known, thus negating unity. See Niemetz et al (Phytochem., 1998) at Table 2.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are based on the identity of the saccharide component "R":

- R = hexose (glucose, mannose, etc.)
- R = pentose (xylose, lyxose, etc.)
- R = sugar alcohol (glucitol or inositol)
- R = disaccharide (trehalose, maltose, etc.)

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. This species election if required regardless of which invention is elected. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. See MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 1-6, 11 and 13-19 correspond to the species wherein R = a hexose (glucose). The following claims are generic: 7-10, 12 and 20-24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature that is novel and contributed by Applicant. The common structural requirement of the compounds used in the methods is a saccharide component covalently attached to a hydroxybenzoic acid moiety. As discussed above, these compounds are known, thus negating

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unity of invention. The species set forth above are patentably distinct based on their structure and non-overlapping in scope.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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## Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 9:00 to 5:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://www.uspto.gov. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier Primary Examiner

January 15, 2008